

12/3/01

Office Action Summary	Application No.	Applicant(s)
	09/182,645	LI ET AL.
	Examiner Shengjun Wang	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 September 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25,28-31,35-38 and 46-49 is/are pending in the application.
- 4a) Of the above claim(s) 1-25,28-31 and 35-38 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 46-49 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted September 5, 2001 is acknowledged.

Applicants are reminded that applicants' election in the parent application (paper No. 9) is presumed to carry over to the instant CPA since applicants have not indicated a contrary intention.

The claims have been examined insofar as they read on the elected species.

Claims 1-25, 28-31, 35-38 and 46-49 are currently pending in the application. Claims 46-49 are read on the elected invention and species. Claims 1-25, 28-31 and 35-38, drawn to non-elected invention, or non-elected species, are withdrawn from further consideration.

Claim Rejection 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 46-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang (DERWENT ACC-NO: 1997-065937, of record), Ning (DERWENT-ACC-NO: 1997-416112, of record) and Tanuma (AB and AC).
2. Wang teaches method of treatment of diabetes comprising administering ginseng to the patient. See the abstract. Ning teaches method of treatment of ischemia comprising administering ginseng to the patient. See the abstract. The ginseng is administered in the form of tea. See both

Art Unit: 1617

abstracts. Tanuma teach that ginseng hot water extract containing the lignin glycoside herein.

See page 5, lines 2-4, the embodiment 1 at page 5, and page 12 in JP 3-205402 the translated copy. Therefore the claimed method herein read on the method taught by Wang and Ning.

Regarding the functional limitation about the detailed enzyme and biochemical function, i.e., inhibitor of poly(ADP-ribose) glycohydrolase, it is well-settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter.

Claim 49 is properly rejected because it is well known in the art that reperfusion injury is a symptom of diabetes. A method known to be useful for treating the underlying etiology, would inherently be useful for treating the symptom caused by the etiology. Further, since the tea disclosed by Ning and Wang are known to be effective for treating ischemia or diabetes, the amounts of lignin glycoside therein would be reasonably be considered therapeutically effective.

Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art."

Claim Rejections 35 U.S.C – 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1617

4. Claims 27, 32-33 and 39-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (DERWENT ACC-NO: 1997-065937) or Ning (DERWENT-ACC-NO: 1997-416112) in view of Tanuma (AB and AC).

5. Wang teaches method of treatment of diabetes comprising administering ginseng to the patient. See the abstract. Ning teaches method of treatment of ischemia comprising administering ginseng to the patient. See the abstract. The ginseng is administered in the form of tea. See both abstracts.

6. The primary references do not teach expressly the employment of lignin glycoside for treatment of diabetes.

7. However, Tanuma teach that the particular PARG inhibitor herein, lignin glycoside, is found in ginseng. See the above discussion. Tanuma further teach that the lignin glycoside is hot water extractable. See page 6 in JP 3-205402 the translated copy. Therefore, it is *prima facie* obvious to use the hot water extractable part for treatment of diabetes. Regarding the functional limitation about the detailed enzyme function, i.e., inhibitor of poly(ADP-ribose) glycohydase, it is well-settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Claim 49 is properly rejected because it is well known in the art that reperfusion injury is a symptom of diabetes. A method known to be useful for treating the underlying etiology, would have been reasonably expected to be useful for treating the symptom caused by the etiology. Further, since the tea disclosed by Ning and Wang are known to be effective for treating ischemia or diabetes, the amounts of lignin glycoside therein would be reasonably be considered therapeutically effective. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated

Art Unit: 1617

"is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." The ultimate utility for the claimed substance is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

Response to the Arguments

8. Applicants' amendments and arguments submitted September 5, 2001 have been fully considered, but are not persuasive for reasons discussed below.
9. Applicants' assertion that the newly added claims 46-49 are not claim the old "thing" (e.g., lignin glycoside) is incorrect. The old "thing" (e.g., lignin glycoside) is a reason the inhibitor of poly(ADP-ribose) glycohydrolase. Further, applicants may not change elected species after receiving the first office action on the merits.
10. Applicants' remarks regarding the Old subject matter and In re Swinehart have been considered, but are not persuasive. Particularly, subject matter may not be interpreted solely as a composition. For example, the old and obvious subject matter herein is a process, which comprises employing a composition comprising lignin glycoside for treating ischemia or diabetes. This is not an issue of using an old composition in a new and unobvious way.
11. Applicants' arguments regarding the rejections under 35 U.S.C. 103 (a) over Tanuma (AB and AC) in view of both Wielckens et al. (BQ), and Wachsman (BO) are moot in view of the new ground of rejection.

Art Unit: 1617

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. This application contains claims 1-25 and 38 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Art Unit: 1617

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Shengjun Wang

AU 1617

November 26, 2001

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

